WE CLAIM:

1. A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

moving said puncturing element in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element such that said puncturing element punctures the vessel wall at the site to be treated with the puncturing element; and

delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall.

2. The method of claim 1 wherein the step of delivering the drug comprises delivering the drug into the vessel wall.

3. The method of claim 1 wherein the step of delivering the drug comprises delivering the drug to the outer surface of the vessel wall.

4. The method of claim 1 wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.

5. The method of claim 1 wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.

6. The method of claim 1 wherein the delivery means includes said puncturing element having a drug

delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.

7. A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

an elongated catheter adapted to be inserted into the vessel;

said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position; and

delivery means coupled to said catheter for delivering a drug outside the inner surface of the vessel wall through a puncture in the vessel wall.

~~8.~~ 27 The device defined in Claim ~~7~~ 26 wherein:

said puncturing element further comprises a puncturing tip for puncturing said vessel wall when said puncturing element is in said puncturing position; and

said catheter further comprises a window through which said puncturing tip extends when said puncturing element is in said puncturing position.

~~9.~~ 28 The device defined in Claim ~~7~~ 26 wherein said catheter further comprises:

an inflatable balloon coupled to said catheter; and

an inflation lumen extending through said catheter for delivering inflation fluid to said balloon.

10. The device defined in Claim 7 further comprising a coupling that moves said puncturing element from its retracted position to its puncturing position.

11. The device defined in Claim 10 wherein said coupling also moves said puncturing element from its puncturing position to its retracted position.

12. The device defined in Claim 11 further comprising a guide that guides said puncturing element to its retracted position.

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~~13~~. The device defined in Claim ~~7~~ wherein:

said puncturing element further comprises an elongated shaft having a proximal and a distal end and an inner shaft lumen, and a needle, attached to said distal end of said shaft, having an inner needle lumen which is in fluid communication with said inner shaft lumen; and

said delivery means comprises said inner shaft lumen and said inner needle lumen.

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~~14~~. The device defined in Claim ~~13~~ wherein said needle further comprises a puncturing tip for engaging and puncturing said vessel wall when said puncturing element is in said puncturing position.

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~~15~~. The device defined in Claim ~~14~~ wherein said puncturing tip includes an opening in communication with said inner needle lumen so that fluid in said inner needle lumen can flow out of said tip opening.

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16. The invention defined in Claim 15 wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen.

33 ~~17~~. The device defined in Claim 30 ~~14~~ wherein said puncturing tip has a beveled edge for puncturing said vessel wall.

34 ~~18~~. The device defined in Claim 26 ~~7~~ wherein said puncturing element comprises a needle having a tip for puncturing said vessel wall.

35 ~~19~~. The device defined in Claim 34 ~~18~~ wherein:

said needle is bent into a substantially U-shape when said puncturing element is in said retracted position; and

said needle is extended out to form a predetermined angle when said needle is in said puncturing position.

36 ~~20~~. The device defined in Claim 34 ~~18~~ wherein:

said needle is bent to a first predetermined angle when said puncturing element is in said retracted position; and

said needle is extended out to form a second predetermined angle when said needle is in said puncturing position.

37 ~~21~~. The device defined in Claim 34 ~~18~~ wherein said needle is substantially parallel with said portion of said catheter when said needle is in said retracted position, said needle also being substantially non-parallel with said portion of said catheter when said needle is in said puncturing position.

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~~22~~. The method of Claim 1 wherein said drug comprises an antiproliferative drug for the treatment of restenosis.

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~~23~~. The method of Claim 1 wherein said drug comprises an antiproliferative drug for the treatment of vascular disease.

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~~24~~. The method of Claim 1 wherein said drug comprises a specific inhibitor of cellular proliferation.

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~~25~~. The method of Claim 1 wherein said drug comprises a specific inhibitor of thrombin.

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~~26~~. The method of Claim 1 wherein said drug comprises a specific inhibitor of platelets.

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~~27~~. The method of claim 1 wherein said drug comprises a genetic material.

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~~28~~. The method of claim 1 wherein said drug comprises a genetic material that when incorporated into cells results in the expression of therapeutic materials.

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~~29~~. The method of claim 1 wherein said drug is incorporated into a time released matrix.

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